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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,327	05/25/2000	Neil H. Riordan	RIORD.004A	7262

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/579,327		RIORDAN ET AL.	
	Examiner		Art Unit	
	Mark Navarro		1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-54, 57-61 and 63-73 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41, 42, 45-51, 58-61 and 63-73 is/are allowed.
- 6) ☒ Claim(s) 40 is/are rejected.
- 7) ☒ Claim(s) 43, 44, 52-54 and 57 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Applicants amendment filed January 28, 2004 has been received and entered. Claims 55-56 and 62 have been canceled and new claims 67-73 have been added. Accordingly, claims 40-54, 57-61, and 63-73 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 55-56 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the cancellation of said claims.
2. The rejection of claims 40-47 and 49-66 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing an immunogenic composition from *L. fermentum*, does not reasonably provide enablement for producing an immunogenic composition from any peptidoglycan containing bacteria is withdrawn in view of Applicants arguments.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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3. The rejection of claim 40 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Link et al is maintained.

It is noted that Applicants amendment to change dependency upon a claim which recites a acid treatment solution with a final pH of about 2.0 is sufficient to withdraw this rejection from claims 41-42, 45-50, 58-61, and 63-65.

Applicants are asserting that the Link reference contains no teaching or suggestion that the immunostimulatory products can be prepared without the presence of lysozyme, which is essential to Link's method. Applicants assert that the present invention, in contrast, is directed to a different immunostimulating composition, which is prepared by treating a bacterial mixture with an acid treatment solution. Applicants finally assert that the compositions of the present invention are in a form that is suitable for administration by injection.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants arguments are not found to be persuasive in view of the disclosure of Link et al.

First, Applicants assert that the Link reference contains no teaching or suggestion that the immunostimulatory products can be prepared without the presence of lysozyme, which is essential to Link's method. However, Applicants are respectfully directed back to the claim. Claim 40 recites a method for producing an immune stimulating composition **comprising...** (Emphasis added). Applicants are reminded that the transitional phrase of comprising allows for other molecules/ingredients to be

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present above and beyond that which is recited in the claims. Link discloses of each and every limitation set forth in the claims, and accordingly is deemed to anticipate the claimed invention.

Second, Applicants assert that the present invention, in contrast, is directed to a different immunostimulating composition, which is prepared by treating a bacterial mixture with an acid treatment solution. However, whether or not the composition is the same or not is not germane. The only question is does Link disclose of each and every limitation recited in the claim. Link disclose of treating bacteria containing peptidoglycan (*L. bulgaricus*) in a solution of pH 5. The resulting solution is then centrifuged, filtered, and its immunostimulating effect determined in mice. (See claims and columns 3-4). Accordingly, each and every limitation has been addressed.

Finally, Applicants assert that the compositions of the present invention are in a form that is suitable for administration by injection. However, Applicants are again directed back to the claims. There is simply no requirement that the composition be suitable for administration by injection.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

The following new grounds of rejection are applied to the amended claims:

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Double Patenting

4. Applicant is advised that should claim 67 be found allowable, claim 54 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 43-44, 52-54, and 57 are objected to for depending upon a rejected base claim, however claims 43-44, 52-54 and 57 are free of the prior art of record.

Claims 67-73, 41-42, 45-51, 58-61, and 63-66 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
April 29, 2004